CLAIMS

What is claimed is:

1. An apparatus for producing a sterilized, prefilled container comprising:

a sterilizing station for sterilizing a container;

a sterile environment comprising an opening for receiving a sterilized container;

a sterile ambient atmospheric condition adjacent the opening;

a transport mechanism for transferring a sterilized container from the sterilizing station to the sterile environment wherein the sterilized container is exposed to the sterile ambient atmospheric condition;

a source of a sterile fluid substance; and

a filler for introducing the sterile fluid substance into a sterilized container while the sterilized container is within the sterile environment.

2. The apparatus of claim 1 wherein the sterilizing station comprises a source of electron beam irradiation.

3. The apparatus of claim 2 further comprising a field of electrons produced by the source of electron beam irradiation wherein the field of electrons sterilizes the container and provides at least a portion of the sterile ambient atmospheric condition.

4. The apparatus of claim 2 wherein the source of electron beam irradiation delivers a dose of 10 kGy to 50 kGy.

5. The apparatus of claim 2 wherein the source of electron beam irradiation delivers a dose of 20 kGy to 40 kGy.

6. The apparatus of claim 2 wherein the source of electron beam irradiation delivers a dose of 15 kGy to 25 kGy.

7. The apparatus of claim 2 wherein the source of electron beam irradiation delivers a dose of 25kGy.

8. The apparatus of claim 4 wherein the dose of electron beam irradiation is delivered at 1 to 10 MeV.

9. The apparatus of claim 4 wherein the dose of electron beam irradiation is delivered at less than 1 MeV.

10. An apparatus for continuous in-line production of a plurality of sterilized, prefilled containers comprising:

a sterilization station comprising a means for continuously sterilizing a plurality of containers;

a sterile isolator comprising an opening for continuously receiving a plurality of containers;

a sterile ambient atmospheric condition adjacent the opening;

a transport mechanism for continuously transferring a plurality of sterilized containers from the sterilizing station to the sterile isolator wherein the plurality of sterilized containers are exposed to the sterile ambient atmospheric condition;

a source of a sterile fluid substance; and

a filler for introducing the sterile fluid substance into a plurality of sterilized containers while the plurality of sterilized containers are within the sterile isolator.

11. The apparatus of claim 10 wherein the means for continuously sterilizing a plurality of containers comprises a source of electron beam irradiation.

12. The apparatus of claim 11 further comprising a field of electrons produced by the source of electron beam irradiation wherein the field of electrons sterilizes the plurality of containers and provides at least a portion of the sterile ambient atmospheric condition.

13. The apparatus of claim 11 wherein the source of electron beam irradiation delivers a dose of 10 kGy to 50 kGy.

14. The apparatus of claim 11 wherein the source of electron beam irradiation delivers a dose of 20 kGy to 40 kGy.

15. The apparatus of claim 11 wherein the source of electron beam irradiation delivers a dose of 15 kGy to 25 kGy.

16. The apparatus of claim 11 wherein the source of electron beam irradiation delivers a dose of 25kGy.

17. The apparatus of claim 13 wherein the dose of electron beam irradiation is delivered at 1 to 10 MeV.

18. The apparatus of claim 13 wherein the dose of electron beam irradiation is delivered at less than 1 MeV.

19. An apparatus for producing sterilized, prefilled syringe bodies comprising:

a sterilizing station for sterilizing a syringe body;

a sterile isolator comprising an opening for receiving a sterilized syringe body;

a sterile ambient atmospheric condition adjacent the opening;

a transport mechanism for transferring a sterilized syringe body from the sterilizing station to the sterile isolator wherein the sterilized syringe body is exposed to the sterile ambient atmospheric condition;

a source of a sterile fluid substance; and

a filler for introducing the sterile fluid substance into a sterilized syringe body while the sterilized syringe body is within the sterile isolator.

20. An apparatus for continuous in-line production of a plurality of sterilized, prefilled syringe bodies comprising:

a sterilization station comprising a means for continuously sterilizing a plurality of syringe bodies;

a sterile isolator comprising an opening for continuously receiving a plurality of syringe bodies;

a sterile ambient atmospheric condition adjacent the opening;

a transport mechanism for continuously transferring a plurality of sterilized syringe bodies from the sterilizing station to the sterile isolator wherein the plurality of sterilized syringe bodies are exposed to the sterile ambient atmospheric condition;

a source of a sterile fluid substance; and

a filler for introducing the sterile fluid substance into a plurality of sterilized syringe bodies while the plurality of sterilized syringe bodies are within the sterile isolator.

21. The apparatus of claim 20 further comprising a transfer holder adapted for receiving a plurality of syringe bodies wherein the transfer holder is sterilized at the same time the plurality of syringe bodies are sterilized by the sterilization station.

22. The apparatus of claim 20 wherein the means for continuously sterilizing a plurality of containers comprises a source of electron beam irradiation.

23. The apparatus of claim 22 further comprising a field of electrons produced by the source of electron beam irradiation wherein the field of electrons sterilizes the plurality of containers and provides at least a portion of the sterile ambient atmospheric condition.

24. The apparatus of claim 22 wherein the source of electron beam irradiation delivers a dose of 10 kGy to 50 kGy.

25. The apparatus of claim 22 wherein the source of electron beam irradiation delivers a dose of 20 kGy to 40 kGy.

26. The apparatus of claim 22 wherein the source of electron beam irradiation delivers a dose of 15 kGy to 25 kGy.

27. The apparatus of claim 22 wherein the source of electron beam irradiation delivers a dose of 25kGy.

28. The apparatus of claim 24 wherein the dose of electron beam irradiation is delivered at 1 to 10 MeV.

29. The apparatus of claim 24 wherein the dose of electron beam irradiation is delivered at less than 1 MeV.

30. An apparatus for directly receiving a molded, polymeric container from a container forming process and producing a sterilized, prefilled container comprising:

a sterilization station comprising a means for sterilizing a container;

a means for transporting a container from a container forming process to the sterilization station;

a sterile isolator comprising an opening for receiving a sterilized container;

a sterile ambient atmospheric condition adjacent the opening;

a transport mechanism for transferring a sterilized container from the sterilizing station to the sterile isolator wherein the sterilized container is exposed to the sterile ambient atmospheric condition;

a source of a sterile fluid substance; and

a filler for introducing the sterile fluid substance into a sterilized container while the sterilized container is within the sterile isolator.

31. The apparatus of claim 30 wherein the sterilizing station comprises a source of electron beam irradiation.

32. The apparatus of claim 31 further comprising a field of electrons produced by the source of electron beam irradiation wherein the field of electrons sterilizes the container and provides at least a portion of the sterile ambient atmospheric condition.

33. The apparatus of claim 31 wherein the source of electron beam irradiation delivers a dose of 10 kGy to 50 kGy.

34. The apparatus of claim 31 wherein the source of electron beam irradiation delivers a dose of 20 kGy to 40 kGy.

35. The apparatus of claim 31 wherein the source of electron beam irradiation delivers a dose of 15 kGy to 25 kGy.

36. The apparatus of claim 31 wherein the source of electron beam irradiation delivers a dose of 25kGy.

37. The apparatus of claim 33 wherein the dose of electron beam irradiation is delivered at 1 to 10 MeV.

38. The apparatus of claim 33 wherein the dose of electron beam irradiation is delivered at less than 1 MeV.

39. A method of in-line, continuous production of sterile prefilled containers, the method comprising the steps of:

providing a container;

sterilizing the container;

providing a sterile environment;

providing a sterile ambient atmospheric condition adjacent the sterile environment;

transferring the sterilized container to the sterile environment while exposing the sterilized container to the sterile ambient atmospheric condition;

providing a source of a medical solution; and

introducing the medical solution into the sterilized container while the sterilized container is within the sterile environment.

40. The method of claim 39 wherein the step of sterilizing the container includes providing a source of electron beam irradiation.

41. The method of claim 40 wherein the step of sterilizing the container includes irradiating the container with a predetermined dose of the electron beam wherein the container is sterilized by the dose of electron beam irradiation and at least a portion of the sterile ambient atmospheric condition includes the predetermined dose of electron beam irradiation.

42. The method of claim 41 wherein the predetermined dose of the electron beam is between 10 kGy and 50 kGy.

43. The method of claim 41 wherein the predetermined dose of the electron beam is 25 kGy.

44. The method of claim 39 further comprising the step of:

sealing the container after the medical solution has been introduced thereto.

45. The method of claim 44 further comprising the step of:

transferring the container from the sterile environment.

46. A sterilized, prefilled container produced according to the method of claim 39.

47. A method of in-line, continuous production of sterile prefilled containers, the method comprising the steps of:

providing a container having no secondary packaging;

sterilizing the container; and

transferring the container to a sterile environment while exposing the container to ambient conditions;

providing a source of a medical solution; and

introducing the medical solution into the sterilized container while the sterilized container is within the sterile environment.

48. The method of claim 47 wherein the step of sterilizing the container includes providing a source of electron beam irradiation.

49. The method of claim 48 wherein the step of sterilizing the container includes irradiating the container with a predetermined dose of the electron beam irradiation wherein the container is sterilized by the dose of electron beam irradiation.

50. The method of claim 49 wherein the predetermined dose of the electron beam irradiation is between 10 kGy and 50 kGy.

51. The method of claim 49 wherein the predetermined dose of the electron beam irradiation is 25 kGy.

52. The method of claim 47 further comprising the step of:

sealing the container after the medical solution has been introduced thereto.

53. The method of claim 50 further comprising the step of:

transferring the container from the sterile environment.

54. A sterilized, prefilled container produced according to the method of claim 47.

55. A method of producing a sterile prefilled container for medical purposes, the method comprising the steps of:

providing a container;

sterilizing the container;

providing a sterile environment;

transferring the sterilized container to the sterile environment while exposing the container to ambient conditions;

providing a fluid substance;

introducing the fluid substance into the container while the container is within the sterile environment; and

sealing the fluid substance within the container while the container is within the sterile environment.

56. The method of claim 55 wherein no human contact with the container is required.

57. The method of claim 55 wherein the sterilizing of the container step includes providing a source of electron beam irradiation and irradiating the container with a predetermined dose of the electron beam irradiation.

58. The method of claim 57 wherein the predetermined dose of the electron beam irradiation is between 10 kGy and 50 kGy.

59. The method of claim 57 wherein the predetermined dose of the electron beam irradiation is 25 kGy.

60. The method of claim 55 wherein the introducing the fluid substance into the container while the container is within the sterile environment step is performed within six days of the sterilizing the container step.

61. The method of claim 60 wherein the fluid substance is a sterile water for injection.

62. The method of claim 61 wherein the sterile water for injection has a pH of solution between 5.0 and 7.0.

63. The method of claim of claim 62 further comprising the steps of:

transferring the container from the sterile environment;

storing the container for a predetermined period of time; and

maintaining a pH of solution of the sterile water for injection within a range of 5.0-7.0.

64. The method of claim 60 wherein the introducing the fluid substance into the container while the container is within the sterile environment step is performed within fifteen minutes after the sterilizing the container step.

65. The method of claim 55 wherein the providing the container step includes forming the container from a polymeric resin.

66. The method of claim 65 wherein the providing container step includes weighing and inspecting the container subsequent to forming the container.

67. The method of claim 66 wherein the forming the container from a polymeric resin includes injection molding the container.

68. The method of claim 65 wherein the polymeric resin is a cyclic olefin copolymer.

69. The method of claim 55 wherein the container is a syringe body.

70. The method of claim 69 further comprising the steps of providing a tip cap for the syringe body and fixing the tip cab to an open tip end of the syringe body.

71. The method of claim 70 further comprising the steps of transferring a sterilized plunger into the sterile environment and inserting the plunger into an open end of the sterile syringe body subsequent to the introducing the fluid substance into the syringe body while the syringe body is within the sterile environment step wherein the the fluid substance is sealed within the syringe body.

72. The method of claim 71 further comprising the step of fixing a plunger rod to the plunger.

73. The method of claim 55 further comprising the steps of transferring the sterilized container from the sterile environment and resterilizing the container subsequent to filling.

74. The method of claim 73 further comprising the steps of labeling the container and packaging the container for delivery to an end user.

75. A prefilled, sterilized container produced according to the method of claim 55.

76. A method of in-line, continuous production of sterile prefilled syringe bodies for medical purposes, the method comprising the steps of:

forming a plurality of syringe bodies by injection molding;

arranging the plurality of syringe bodies in a predetermined order on a transfer mechanism;

transferring the plurality of syringe bodies along the transfer mechanism to a sterilizing location;

sterilizing the plurality of syringe bodies;

transferring the plurality of sterilized syringe bodies to a sterile environment while maintaining the plurality of syringe bodies in a sterilized condition;

providing a fluid substance within the sterile environment;

introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment; and

sealing the fluid substance within the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment.

77. The method of claim 76 wherein the transfer mechanism includes a conveyor belt.

78. The method of claim 77 wherein no human intervention is required.

79. The method of claim 78 wherein the sterilizing of the plurality of syringe bodies step includes providing a source of electron beam irradiation and irradiating the plurality syringe bodies with a predetermined dose of the electron beam irradiation.

80. The method of claim 79 wherein the predetermined dose of the electron beam irradiation is between 10 kGy and 50 kGy.

81. The method of claim 80 wherein the predetermined dose of the electron beam irradiation is 25 kGy.

82. The method of claim 80 wherein the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step is performed within six days of the sterilizing the plurality of the syringe bodies step.

83. The method of claim 82 wherein the fluid substance is a sterile water for injection.

84. The method of claim 83 wherein the sterile water for injection has a pH of solution between 5.0 and 7.0.

85. The method of claim of claim 84 further comprising the steps of:

transferring the plurality of syringe bodies from the sterile environment;

storing the plurality of syringe bodies for a predetermined period of time; and

maintaining a pH of solution of the sterile water for injection within a range of 5.0-7.0.

86. The method of claim 80 wherein the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step is performed immediately after the sterilizing the plurality of syringe bodies step.

87. The method of claim 80 wherein the plurality of syringe bodies are formed from a polymeric resin.

88. The method of claim 87 wherein the polymeric resin is a cyclic olefin copolymer.

89. The method of claim 88 further comprising the step of weighing and inspecting the plurality of syringe bodies subsequent to forming the syringe body.

90. The method of claim 80 further comprising the steps of providing a tip cap for each of the plurality of the syringe bodies and fixing the tip cab to an open tip end of each of the plurality of syringe body.

91. The method of claim 90 further comprising the steps of transferring a plurality of sterilized plungers into the sterile environment and inserting at least on of the plurality of plungers into an open end of each of the plurality of sterile syringe bodies subsequent to the introducing the fluid substance into the plurality of syringe bodies while the plurality of syringe bodies are within the sterile environment step wherein the fluid substance is sealed within the plurality of syringe bodies.

92. The method of claim 91 further comprising the step of fixing a plunger rod to each plunger.

93. The method of claim 80 further comprising the steps of transferring the sterilized plurality of syringe bodies from the sterile environment and resterilizing the plurality of syringe bodies subsequent to filling.

94. The method of claim 93 further comprising the steps of labeling the plurality of syringe bodies and packaging the plurality of syringe bodies for delivery to an end user.

95. A method of continuously producing a plurality of sterile prefilled syringe bodies for medical purposes, the method comprising the steps of:

providing a plurality of syringe bodies;

arranging the plurality of syringe bodies within a transfer tray;

sterilizing the plurality of syringe bodies and the transfer tray substantially simultaneously;

transferring the plurality of sterilized syringe bodies and the sterilized transfer tray to a sterile environment while exposing the plurality of syringe bodies and the transfer tray to a sterile ambient atmospheric condition;

providing a fluid substance; and

introducing the fluid substance into each syringe body individually while the plurality of syringe bodies are within the sterile environment.

96. A method of continuously producing a plurality of sterile prefilled syringe bodies for medical purposes, the method comprising the steps, in sequence of:

providing a syringe body;

sterilizing the syringe body;

transferring the sterilized syringe body to a sterile environment while exposing the syringe body to a sterile ambient atmospheric condition;

providing a fluid substance; and

introducing the fluid substance into the syringe body while the syringe body is within the sterile environment.

97. A method of providing a prefilled polymeric container and controlling a solution pH of a sterile, parenteral solution within the polymeric container, the method comprising the steps of:

providing a container produced from a polymeric material where an ionizing radiation causes the formation of free radicals on the container;

providing a source of ionizing radiation;

sterilizing the polymeric container with a predetermined dose of the ionizing radiation;

providing a source of a parenteral solution;

introducing the parenteral solution into the container within 48 hours of sterilizing the polymeric container with a predetermined dose of the ionizing radiation; and

sealing the parenteral solution within the polymeric container.

98. The method of claim 97 wherein the ionizing radiation is an electron beam, irradiation.

99. The method of claim 98 wherein the predetermined dose of electron beam irradiation is between 10 kGy and 50 kGy.

100. The method of claim 99 wherein the predetermined dose of the electron beam irradiation is 25 kGy.

101. The method of claim 97 wherein the introducing the parenteral solution into the polymeric container is performed within 24 hours of the sterilizing the container step.

102. The method of claim 97 wherein the introducing the parenteral solution into the polymeric container is performed within 15 minutes of the sterilizing the container step.

103. The method of claim 102 wherein the parenteral solution has a pH of solution between 5.0 and 7.0.

104. A prefilled, sterile container produced according to the method of claim 97.